K112073

APR 11 2012

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: July 6, 2011

Applicant: Rx Devices LLC
2030 Oakes Blvd.
Naples, FL 34119

Contact Individual: Charles Hokanson, CEO (610 715-3263)
hokanson@earthlink.net

Trade Name: InfuSite Needleless Access Device

Common Name: Needleless Access Device

Regulation Number: 880.5440

Product Code: FPA

Classification Name: Set, Administration, Intravascular

Classification: Class II

Predicate Device Name: Smartsite K960280, Swabsite K002689

Device Description:

The InfuSite Needleless Access Device is a closed system needleless multi-purpose catheter accessory, permitting blood sampling, intermittent injection or continuous infusion of fluids or medications. Connection is exclusively with the Luer systems. The InfuSite Needleless Access Device has a polycarbonate male/female luer housing with a swabable silicone membrane, which opens automatically upon connection with a male luer and closes automatically when the male luer is disconnected. Disinfection must be carried out before and after use. The InfuSite contains no metallic components.

Intended Use:

The InfuSite Needleless Access Device is a closed system needleless accessory, which permits blood sampling, intermittent injection or infusion of fluids or medications when connected exclusively to luer systems.

Technology Characteristics:

The InfuSite Needleless Access Device is substantially equivalent to the predicate devices. No new materials or new issues of safety and efficacy have been introduced with this device.

Summary of Design Control Activities:

The Infusite was designed and developed in accordance ISO and FDA design control guidelines. Biocompatibility data demonstrates that the materials used are non-irritant and non-toxic. Performance testing demonstrates that the device is substantially equivalent to the predicate devices (SmartSite, K960280, Swabsite K002689). Risk Assessment was conducted in compliance with ISO 14971.

Conclusion:

The indications for use are identical to the predicate devices. The materials and technology of the InfuSite Needleless Access Device are equivalent to the predicate devices and no new issues of safety and efficacy have been introduced with this device. Biocompatibility testing, performance testing and risk assessment demonstrate that the InfuSite Needleless Access Device is substantially equivalent to the predicate devices, and safe and effective, when used in accordance with the supplied instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Charles Hokanson
CEO
Rx Devices LLC
2030 Oakes Blvd.
Naples, Florida 34119

APR 11 2012

Re: K112073
Trade/Device Name: InfuSite Needleless Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 12, 2012
Received: March 14, 2012

Dear Mr. Hokanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: InfuSite Needleless Access Device

Indications For Use:

The InfuSite Needleless Access Device is a closed system needleless accessory, which permits blood sampling, intermittent injection or infusion of fluids or medications when connected exclusively to luer systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 4/12/12
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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